DETAILED ACTION

Status of Claims

Claims 1-29 and 31-126 are pending. Claims 1-8, 10-12, 15-19, 22-25, 29, 31-33, and 36 are rejected. Claims 9 and 30 are cancelled. Claims 13, 14, 20, 21, 26-28, 34, 35, and 37-126 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Withdrawn Rejections

The rejection of claims 1-4, 7-8, 10-12, 15-17, 19, 22-25, 29, 32, 33, and 36 under 35 U.S.C. 103(a) as being unpatentable over Eggert et al. in view of Varelis et al. is withdrawn in view of applicant's amendments, filed 07/15/2008.

The rejection of claims 1-4, 7, 8, 10-12, 15-19, 22-25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine in view of Varelis et al. and Siregar et al. is withdrawn in view of applicant's amendments, filed 07/15/2008.

The rejection of claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine in view of Varelis et al., Siregar et al., and Ivlev et al. is withdrawn in view of applicant's amendments, filed 07/15/2008.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

This is a new ground of rejection.

Claims 1-12, 15-19, 22-25, 29, 31-33, and 36 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

Claims 1-12, 15-19, 22-25, 29, 31-33, and 36 are drawn to a method. For a process to be statutory, it must provide: (1) a practical application that recites a physical transformation of matter (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)]. As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result. The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to (i.e. a process, machine, manufacture, or composition of matter) but rather on the essential characteristics of the subject matter, in particular, and its practical utility. Therefore, for a system or program carrying out a process to be statutory it must also provide a concrete, tangible, and useful result.

In the instant case, claims 1-12, 15-19, 22-25, 29, 31-33, and 36 recite steps directed to operating a simulated organ, comparing data, determining a match, and operating a simulated organ in a different

mode, all of which all may occur inside of a computer. Therefore, the claimed methods do not recite a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). However, claim 1 results in operating a simulated organ wherein a second output is obtained. This is not a tangible result because nothing is communicated to a user in a user readable format. Therefore the claimed method is not statutory. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a user in a user readable format, or outputted to a display.

Claims 1-12, 15-19, 22-25, 29, 31-33, and 36 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

Claims 1-12, 15-19, 22-25, 29, 31-33, and 36 are non-statutory because they read on abstract ideas. The prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (See In re Comiskey, Fed. Cir., No. 2006-1286, 9/20/07; Gottschalk v. Benson, 409 U.S. 63, 175 USPQ 673, 1972).

In the instant case, Claims 1-12, 15-19, 22-25, 29, 31-33, and 36 do not qualify as a statutory process because the method steps that are critical to the invention are "not limited to a particular apparatus or machine." To qualify as a statutory process, the critical method steps recited in claims 1-12, 15-19, 22-25, 29, 31-33, and 36 should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject mater that is being transformed, for example by identifying the material that is being changed to a

different state or thing. Nominal data gathering or post solution activity steps in the claimed subject

matter will not be considered sufficient to convert a process that otherwise recites only mental steps into

statutory subject matter. Preamble limitations that require the claimed process to comprise machine

implemented steps will not be considered sufficient to convert a process that otherwise recites only

mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter

in an amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set

forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7, 8, 10-12, 15-19, 22-25, 29, 33, 36 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Siregar et al. (Computers And Biomedical Research, 1998, Vol. 31, p. 323–347), in

view of Tompkins (Biomedical Digital Signal Processing, Prentice Hall, 2000, Ch. 13, p. 265-282).

This is a new ground of rejection.

The instantly rejected claims are drawn to a method for operating a simulated organ in a first mode corresponding to a first abnormal condition, comparing the first simulation output to obtained obtaining biological measurement data of a user, determining that a user is experiencing the first abnormal condition if there is a match between a first simulation output and obtained biological measurement data, wherein the user is informed of the deduced condition determination, and operating the simulated organ in a second mode corresponding to a second abnormal condition if there is no match, wherein a second simulation output is obtained. It is noted that the specification does not provide a limiting definition for the term "simulated organ". For purposes of examination, "simulated organ" is interpreted as a mathematical model of an organ.

Siregar teaches a method for operating a simulated-cardiac model (i.e. simulated organ) representing a plurality of biological conditions based on patient measurement data, and matching models to patient data [Abstract and p.327, ¶1]. In particular, Siregar teaches operating a simulated heart in normal and abnormal states [Fig. 10-14]. Siregar shows the incorporation their model viewing system with diagnostic software for comparing a selected model to real patient data [p.339]. Siregar teaches models can be adjusted to real patient data (i.e. personalization) [p.329, lines 3-5], and matching simulated data with obtained biological data [p.334]. Siregar teaches control points for calibrating models to real patient data [Fig. 2]. Siregar teaches simulation of a heart and thorax [Fig. 2, 4, 10, 11, 12]. Siregar teaches simulated output that is like a reduced lead set electrocardiogram reading [p.337, ¶3, Fig. 10]. The user can also interactively select a specific model region of the heart and real patient data for matching real and simulated data [p.339 and Fig. 2]. Siregar teaches obtaining real patient data [p.329, lines 3-5].

Siregar does not specifically teach determining that a user is experiencing the first abnormal condition if there is a match between a first simulation output and obtained biological measurement data, wherein the user is informed of the deduced condition determination, and operating the simulated organ in a second mode corresponding to a second abnormal condition if there is no match, wherein a second simulation output is obtained, as in claim 1.

Siregar does not teach preprocessing of biological measurement data, as in claim 18.

Siregar does not specifically teach simulating a cardiopulmonary system, as in claim 36. However, this limitation would have been obvious to one of ordinary skill in the art since Siregar shows modeling the heart as well as aorta and pulmonary trunk [p.329-330], which suggests simulating the cardiopulmonary system, as in claim 36.

Tompkins teaches portable arrhythmia monitors and mathematical models for processing patient data to determine arrhythmia [p.276-277]. In particular, Tompkins teaches mathematical model of the heart (i.e. simulated organ) extracted from patient ECG data to output a first template waveform (i.e. first simulation output), which shows operating a simulated organ in a first mode corresponding to a particular condition. This template model is compared to real-time ECG data to determine possible matches [p.276, ¶ 5]. Matching waveforms represent normal QRS complexes, as in claim 1. Tompkins teaches preprocessing of noisy ECG signal data to remove baseline drift [p.265, Section 13.1.1]. Tompkins does not specifically teach operating the simulated organ in a second mode corresponding to a second abnormal condition if there is no match, wherein a second simulation output is obtained, as in claim 1. However, this limitation would have been obvious to one of ordinary skill in the art since Tompkins teaches non-matching waveforms representing abnormal complexes output as abnormal templates (i.e. second simulation output) for comparison to future suspected abnormal QRS complexes [p.276, ¶ 5, Fig. 13.10].

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the method of Siregar using the waveform matching techniques taught by Tompkins, since Siregar suggests an analysis framework that can be applied to the diagnosis of heart disease [p.342, Section VI] and that quantitative analysis of ECG data is critical for using non-invasive means for diagnosing patients [p.339]. The motivation would have been to improve diagnostic models with commonly used algorithms for matching real patient data and simulated data, as suggested by Siregar [p.339 and Fig. 2] and Tompkins [p.276].

Claims 1-8, 10-12, 15-19, 22-25, 29, 31-33, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siregar et al. (Computers And Biomedical Research, 1998, Vol. 31, p. 323–347), in view of Tompkins (Biomedical Digital Signal Processing, Prentice Hall, 2000, Ch. 13, p. 265-282), as applied to claims 1-4, 7, 8, 10-12, 15-19, 22-25, 29, 33, 36 above, and further in view of Platt et al. (WO 89/00061, 1989, IDS filed 09/30/2004).

This is a new ground of rejection.

Siregar and Tompkins make obvious a method for operating a simulated organ, as set forth above.

Siregar and Tompkins do not teach simulating the simulated organ at a wireless node or server, as in claims 5, 6, and 31.

Siregar and Tompkins do not teach a plurality of operational modes for the simulated organ that are iteratively selected, as in claim 32.

Platt teaches a method for comparing pace maker waveform signals (i.e. simulated organ) with ECG waveforms from a living individual [p.2]. In particular, Platt teaches infrared and RF radio links for the wireless communication of data to remote data processing center (i.e. servers) [p.12, ¶5], which makes obvious the simulation of data at wireless nodes and servers, as in claims 5, 6, and 31. Platt also

teaches a mode switch to toggle between pacemaker signals and biological measurement signals [p.8, ¶3] and as well as operational modes for modeling data (e.g. APW, VPW) [p.10-11], which makes obvious the iterative selections of different operational modes, as in claim 32, since the modes are user selectable.

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the method made obvious by Siregar and Tompkins using the communications system taught by Platt, since Levine shows using communications network in combination with simulation systems [0023, 0065]. The motivation would have to improve diagnostic models by using wireless networks and servers to allow for the remote access and distribution of information, as suggested by Platt [p.12, ¶5].

Response to Arguments

Applicant's arguments, filed 07/15/2008, that the cited references fail to disclose all aspects of claim 1 in view of applicant's amendments has been fully considered but is moot in view of the new grounds of rejections.

Applicant's arguments, filed 07/15/2008, fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631